

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0322371	(X3) Date Survey Completed 02/14/2018
Name of Provider or Supplier Ephraim Mcdowell Mercer Pediatrics	Street Address, City, State 466 Linden Avenue, Harrodsburg, KY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing results from Wisconsin State Laboratory Hygiene (WSLH) proficiency testing agency and staff interview on 02/14/2018, the laboratory failed to ensure proficiency testing samples were tested by all three personnel who routinely perform Complete Blood Cell (CBC) patient testing. Findings include: Review of attestation statements revealed the same person tested all of the samples for three Hematology testing events in 2016 and three Hematology testing events in 2017. Testing personnel acknowledged in an interview at 11:15 AM on 02/14/2018, the laboratory failed to have a system in place to ensure proficiency testing samples were rotated among all testing personnel responsible for CBC testing.</p>
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview on 02/14/2018, the laboratory failed to test</p>

at least two levels of quality control material on the Beckman-Coulter AcT Diff hematology instrument on two of six days of patient Complete Blood Count (CBC) testing. Findings include: Review of patient test reports revealed two patient CBCs were reported on 12/16/2016 and only results for the Hi control were available. Review of patient test reports revealed nine patient CBCs were reported on 06/23 /2017 and only results for the Normal control were available. Testing personnel acknowledged in an interview at 11:15 AM on 02/14/2018, the laboratory failed to have a system in place to ensure at least two levels of quality control material were tested each day prior to patient testing.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on record review and staff interview on 02/14/2018 , the Technical Consultant failed to perform and document annual competency using the six mandated competency assessment requirements for testing personnel. Findings include: Review of personnel files revealed competency assessment was not performed for three out of three employees from Jan 1, 2017 through December 31, 2017, to include direct observation of patient test performance, monitoring the recording and reporting of test results, review of worksheets, quality control records, proficiency test results, and maintenance records, direct observation of maintenance and function checks, assessment of testing external proficiency testing samples, and assessing the skills for solving problems. Testing personnel acknowledged in an interview at 11:30 AM on 02 /14/2018, the laboratory failed to have a system in place to ensure annual competency assessment was performed using the six mandated assessment requirements.